UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

SUBJECT: [Updated] Existing Chemical Exposure Limit (ECEL) for Occupational Use of

Trichloroethylene

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EPA has developed an 8-hour existing chemical exposure limit (ECEL) Ex. 5 Deliberative Process (DP) efforts on trichloroethylene under TSCA section 6(a), 15 U.S.C. §2605. EPA calculated the ECEL to be 4.0 ppb (0.021 mg/m3) for inhalation exposures to trichloroethylene as an 8-hour time-weighted average (TWA) and for use in workplace settings (see Appendix A) based on the acute non-cancer occupational human equivalent concentration (HEC99) for congenital heart defects. Ex. 5 Deliberative Process (DP)

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Ex. 5 Deliberative Process (DP) ([HYPERLINK "https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/final-risk-evaluation-trichloroethylene" \l "documents") Ex. 5 Deliberative Process (DP)

EPA expects that at the acute non-cancer ECEL of (k)(5) a worker or occupational non-user (ONU) is also protected against congenital heart defects resulting from chronic occupational exposure. In addition, this ECEL protects against excess risk of cancer above the $1x10^{-4}$ benchmark resulting from lifetime exposure if ambient exposures are kept below this ECEL.

The Occupational Safety and Health Administration (OSHA) set a permissible exposure limit (PEL) as both an 8-hour TWA and an acceptable ceiling concentration for trichloroethylene ([HYPERLINK "https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1000TABLEZ2"]). However, as noted on OSHA's website, "OSHA recognizes that many of its permissible exposure limits (PELs) are outdated and inadequate for ensuring protection of worker health. Most of OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970 and have not been updated since that time." EPA's ECEL is a lower value and is based on newer information and analysis, from the 2020 [HYPERLINK "https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/final-risk-evaluation-trichloroethylene" \lambda "documents"].

Published NIOSH/OSHA/EPA methods were identified and the ECEL is within the limit of detection (LOD) of some of the methods identified in Appendix B.

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Appendix A: ECEL and Other Exposure Limit Calculations

This appendix presents the calculations used to estimate the ECEL and other exposure limits used for comparison. The resulting ECEL value was rounded. The values used in the equations are included in the Final Risk Evaluation for Trichloroethylene ([HYPERLINK "https://www.epa.gov/assessing-andmanaging-chemicals-under-tsca/final-risk-evaluation-trichloroethylene" \l "documents"]).

Acute Non-Cancer ECEL

The 8-hour ECEL is the concentration that EPA

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

The ECEL was calculated for (the acute non-cancer occupational human equivalent concentration (HEC99) for congenital heart defects) Ex. 5 Deliberative Process (DP) at which the acute MOE would equal the benchmark MOE for chronic occupational exposures with the following equation:

$$EL_{acute} = \frac{HEC_{acute,occupational}}{Benchmark\ MOE_{acute}} * \frac{AT_{PODacute}}{ED} = \frac{.0037\ ppm}{10} * \frac{\frac{24h}{d}}{\frac{8h}{d}} = 0.0011\ ppm = 1.1ppb$$

$$ECEL\left(\frac{\text{mg}}{\text{m}^3}\right) = \frac{ECEL\ ppm\ *MW}{Molar\ Volume} = \frac{0.0011\ ppm\ *131.39 \frac{g}{mol}}{24.45 \frac{L}{mol}} = 0.0059\ \frac{\text{mg}}{\text{m}^3}$$

Where:

= 24.45 L/mol, the volume of a mole of gas at 1 atm and 25 °C = Molecular weight of TCE (131.39 g/mole) Molar Volume

MW Molecular weight of TCE (131.39 g/mole)

Chronic Non-Cancer Exposure Limit

The chronic occupational exposure limit (EL____ was calculated as the concentration at which the chronic MOE would equal the benchmark MOE for chronic occupational exposures using the following equation:

$$ECEL_{inhal,occupational} = \frac{HEC_{chronic,occupational}}{Benchmark\ MOE_{chronic}} * \frac{AT_{POD\ chronic}}{ED*EF*WY} =$$

$$\frac{0.0037 \text{ ppm}}{10} * \frac{24h/d*365d/y*40 y}{8h/d*250d/y*40 y} = 0.0016 \text{ ppm} = 1.6 \text{ ppb} = 0.0086 \frac{\text{mg}}{\text{m}^3}$$

Lifetime Cancer Exposure Limit

The EL_{cancer} is the concentration at which the extra cancer risk is equivalent to the benchmark cancer risk of 1×10^{-4} :

$$\mathrm{EL_{cancer}} = \frac{Benchmark_{Cancer}}{IUR} * \frac{AT_{IUR}}{ED*EF*WY} = \frac{1X10^{-4}}{2.2 \times 10^{-2} \ per \ ppm} * \frac{24h/d*365d/y*78y}{8h/d*250d/y*40y} = 0.039 \ ppm = 0.21 \frac{mg}{m^3}$$

Where:

AT_{PODehronic} Averaging time for the POD/HEC used for evaluating non-cancer,

> chronic occupational risk, based on study conditions and/or HEC adjustments (8 hrs/day for 365 days/yr) and assuming the number of years matches the high-end working years (WY, 40 yrs) for a

worker (RE Section 2.3.1.2.4 and Table 2-17).

ATPODacute Averaging time for the POD/HEC used for evaluating non-cancer, acute

occupational risk, based on study conditions and/or any HEC adjustments

(8hrs/day)

AT_{IUR} Averaging time for the cancer IUR, based on study conditions and any

adjustments (24 hrs/day for 365 days/yr) and averaged over a

lifetime (78 yrs) (RE Section 2.3.1.2.4 and Table 2-17)

Benchmark MOE_{acute} Acute non-cancer benchmark margin of exposure, based on the total

uncertainty factor (UF) of 10 (RE Table 3-16)

Benchmark MOE_{chronie} = Chronic non-cancer benchmark margin of exposure, based on the total

uncertainty factor (UF) of 30 (RE Table 3-16)

Benchmark for excess lifetime cancer risk $(1x10^{-4})$ Benchmark Cancer ECEL Existing chemical exposure limit (mg/m³ or ppm) == ELacute Exposure limit based on acute immunosuppression

Exposure limit based on excess cancer risk ELcancer

ED Exposure duration (8 hrs/day), (RE Table 2-17 and Appendix M) EF Exposure frequency (250 days/yr), (RE Table 2-17 and Appendix M) Human equivalent concentration for acute or chronic occupational HECacute or chronic,

occupational exposure scenarios (RE Table 3-16)

Inhalation unit risk (per ppm) (RE Table 3-15) **IUR**

Working years per lifetime at the 95th percentile (40 yrs) WY

(RE Table 2-17)

Unit conversion:

1 ppm = 5.37 mg/m³ (based on molecular weight of 131.39.8 g/mol for TCE and molar volume of 24.45 L/mol at 25°C and 1 atm pressure) $ECEL\left(\frac{mg}{m^3}\right) = \frac{ECEL\ ppm\ *MW}{Molar\ Volume}$

References

U.S. Environmental Protection Agency. 2020. Risk Evaluation for Trichloroethylene (TCE) CASRN: 79-01-6. EPA-740-R1-8008. Office of Chemical Safety and Pollution Prevention. November 2020. Available at: EPA-HQ-OPPT-2019-0500-0113.

U.S. Environmental Protection Agency. 2002. A Review of the Reference Dose and Reference Concentration Processes. Final Report. EPA/630/P-02/002F. Prepared for the Risk Assessment Forum. December.

Appendix B: Summary of Air Sampling Analytical Methods Identified

EPA conducted a search to identify relevant NIOSH/OSHA/EPA analytical methods used to monitor for the presence of trichloroethylene in air (see [REF _Ref61333809 \h * MERGEFORMAT]). The sources used for the search included the following:

- 1) NIOSH Manual of Analytical Methods (NMAM); 5th Edition
 - URL: [HYPERLINK "https://www.cdc.gov/niosh/nmam/default.html"]
- 2) NIOSH NMAM 4th Edition
 - URL: [HYPERLINK "https://www.cdc.gov/niosh/docs/2003-154/default.html"]
- 3) OSHA Index of Sampling and Analytical Methods
 - URL: [HYPERLINK "https://www.osha.gov/dts/sltc/methods/"]
- 4) EPA Environmental Test Method and Monitoring Information
 - [HYPERLINK "https://www.epa.gov/emc/epa-websites-environmental-test-method-and-monitoring-information"]

Table [SEQ Table * ARABIC]: Limit of detection (LOD) summary for air sampling analytical methods identified.

Air Sampling Analytical	Year	LOD ^a	Notes	Source
Methods	Published			
NIOSH Method 8300 [2016	0.43 ppm	Method reports	NIOSH Manual of
HYPERLINK			approximate LOD for	Analytical Methods
"https://www.cdc.gov/nios		4 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	an absorption length of 10 m.	(NMAM); 5th Edition [
h/docs/2014-			10 III.	HYPERLINK
151/pdfs/methods/3800.pd				"https://www.cdc.gov/nios
f"]				h/nmam/default.html"]
NIOSH Method 1022, Issue	1994	60 ppb	Method reports	NIOSH NMAM 4th Edition
2 [HYPERLINK			estimated LOD as 0.01	[HYPERLINK
"https://www.cdc.gov/nios			mg per sample, with a	"https://www.cdc.gov/nios
h/docs/2003-			maximum sample of 30 L.	h/docs/2003-
154/pdfs/1022.pdf"]				154/default.html"]
NIOSH Method 3701, Issue	1994	0.1 ppm	Method reports	NIOSH NMAM 4th Edition
2 [HYPERLINK			estimated LOD as 0.1	[HYPERLINK
"https://www.cdc.gov/nios			ppm for a 1 mL injection.	"https://www.cdc.gov/nios
h/docs/2003-			injection.	h/docs/2003-
154/pdfs/3701.pdf"]	1000	. =		154/default.html"]
OSHA Method 1001 [1999	3.7 or 18	Method reports LOD of	OSHA Index of Sampling
HYPERLINK		ppb	overall procedure as 3.7 ppb for charcoal tubes	and Analytical Methods [
"https://www.osha.gov/dts			and 18 ppb for SKC	HYPERLINK
/sltc/methods/mdt/mdt100			575-002 Samplers.	"https://www.osha.gov/dts
1/1001.html"]			*	/sltc/methods/"]
EPA Method TO-14A	1999	14 ppb	Estimated LOD based	EPA Air Toxics –
[HYPERLINK			on 1 microliter sample	Monitoring Methods
"https://www3.epa.gov/ttn			volume (Table B-1).	[HYPERLINK
/amtic/files/ambient/airtox				"https://www3.epa.gov/ttn
/to-14ar.pdf"]	1000	-0.51	T1:C1	/amtic/airtox.html"]
EPA Method TO-15	1999	≤0.5 ppb	To qualify under	EPA Air Toxics –
[HYPERLINK			Compendium Method TO-15, the method	Monitoring Methods [HYPERLINK
"https://www3.epa.gov/ttn			detection limit must	LITTERLINK
		<u> </u>	detection milit must	

Air Sampling Analytical Methods	Year Published	LODª	Notes	Source
/amtic/files/ambient/airtox /to-15r.pdf']			≤0.5 ppbv. This method uses ppbv, but LODs for other methods listed here are also understood to be on a volume basis. For consistency, the LOD for this method is listed as ≤0.5 ppb.	"https://www3.epa.gov/ttn/amtic/airtox.html"]
EPA Method TO-17	1999	≤0.5 ppb	To qualify under Compendium Method TO-17, the method detection limit must be ≤0.5 ppb.	EPA Air Toxics – Monitoring Methods [HYPERLINK "https://www3.epa.gov/ttn /amtic/airtox.html"]

ppm = parts per million; ppb = parts per billion; ppt = parts per trillion

a EPA has included all relevant NIOSH/OSHA/EPA methods that it identified, including those methods with an LOD above the ECEL.